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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation:

The proposed amendments will not be entered because they do not place the application in better form for allowance or appeal. Particularly, the amendments are made on withdrawn claims. The request for reconsideration has been considered but does NOT place the application in condition for allowance because of the reasons below. Thus, all rejection of claims 1, 3, 5-7 and 10 are upheld.

> The Applicant argues that Hancock and Baba are not analogous art and there is no suggestion that a skilled artisan would make a modification of Hancock with the CCR5 antagonist of Baba in the manner proposed by the Office. Further an "effective amount" of a CCR5 antagonist is not taught as defined in the specification. The Applicants insist that the rejection is similar to an "obvious to try" rejection, in which the Office has not provided guidance for combining a G1 phase arresting agent with an antiviral agent that inhibits entry of HIV into the T-cell. The Applicants have surprisingly found that the addition of RAPA increases the level of chemokines. In regards to Vezina, the major effect of the reference is the loss of CD4+ cells which is a problem for subjects suffering with HIV because of the diminishment of immune response. Applicant's question why a skilled artisan would combine the Vezina and Baba references especially because Baba must have viable T cells with CCR5 receptors and Vezina causes the elimination of T-cells that express the CD4 and CCR5 receptors. Thus, the Office is not allowed to pick and choose just certain parts of different references and combine them. According to the Office, a skilled artisan would read the Baba reference and immediately disregard use of AZT of Vezina and instead use TAK 779 even if Vezina never shows the effectiveness of such combination. The Applicant's have provided evidence of effectiveness with the combination of RAPA and TAK 779. Thus, the Applicant would like the method claims rejoined with the composition claims. The Examiner has shown a non-statutory hindsight analysis.

The Examiner disagrees because as noted in the previous office action and above, the intended use does not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition. The reasons for combining the prior art does not need to the same as the Applicant's. Thus, the "effective amount" is the amount sufficient to achieve a desired therapeutic effect (see Hancock, paragraph 68).

In regards to Hancock and Baba not being analogous art, Hancock provides the teaching of combining the two elements of the claimed invention (at least one G1 phase arresting compound and at least one HIV viral entry inhibitor) in a composition. Baba provides the teaching that TAK 779 (Applicant's elected HIV viral entry inhibitor) is a specific CCR5 antagonist. Thus, one skilled in the art would be able to use any CCR5 antagonist with any immunosuppressant to provide a method for inhibiting the rejection of transplanted grafts. The motivation to use TAK 779 is because it is a specific CCR5 antagonist, so the action is minimized to the target receptor. Further Baba teaches that it is a potent and selective anti-HIV agent (see abstract).

In regards to the Applicant's unexpected results, it is noted that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir.

1983). In this case, the current claims are broad were as the unexpected results are demonstrated with a very specific combination.

In regards to the teaching of Vezina and combining it with Baba, the Examiner has taken both teachings as a whole. Particularly, Vezina teaches that by using cytotoxic doses of rapamycin for limited periods of time (see page 3, lines 5-7) HIV is not able to replicate (see page 3, lines 25-26). Therefore, providing the use of rapamycin for treating, arresting the development or retarding the progression of AIDS in a mammal (see page 4, lines 19-22). Vezina also teaches that rapamycin can be combined with another anti-HIV agent (see abstract and claims 1 and 3). Thus, combining rapamycin with another drug that supports protection of the immune system would obviously be effective. No where in Vezina does it teach that all or most of the T-cells are killed or so badly effected that the patient is not treated. In regards to the specific use of TAK 779 as the additional anti-HIV agent to be used in Vezina, one would be motivated to use TAK 779 because Baba teaches that TAK 779 is a selective and highly potent anti-HIV agent (see Baba, abstract).

In regards to a rejoinder, Hancock and Vezina teach a pharmaceutical composition comprising rapamycin in combination with a CCR5 antagonist or another anti-HIV agent. Baba et al. provides the motivation for choosing the elected CCR5 antagonist (i.e. anti-HIV agent), TAK-779. Thus, since the product claims are not deemed patentable, rejoinder of the method claims are not deemed proper.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

/SREENI PADMANABHAN/

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